REMARKS

First, Applicant would like to thank the Examiner for her time and consideration in the Interview of November 15, 2005. This paper is in response to the outstanding action dated September 30, 2005. The Examiner objected to the specification because the continuing information on the first page contained a gap in the information presented in Applicant's last amendment. In the Interview of November 15, 2005, the Examiner clarified that notwithstanding that the present case was a 371 National Stage filing of a PCT application, the PCT application information still needed to be recited. Applicant has amended paragraph 0001 to now include the PCT application information so that the objection to the specification is now overcome.

The Action of September 30, 2005 also indicated that the references which were submitted with the Amendment of July 7, 2005 were not properly submitted for listing on the patent document via an IDS because it lacks a statement under 37 CFR 1.97(e). The action also stated "It has been placed in the application file, but the information referred to therein has not been considered." Applicant briefly mentioned that the references were submitted as support for the argument that there was a considerably long period of time when the deficiencies of the art were known, yet not met by the technology. The Examiner indicated that the references were considered in the context of that argument, but not beyond and that if applicant wished to have the references listed on the patent document as considered, that either the statement and/or fee as required would need to be submitted. Applicant agreed to do so.

The Action of September 30, 2005 rejected claims 21-36, 39-42, 55, 64, and 73-74 under 35 USC 103 as obvious over Deeds (US 5,524,755) in view of Miller (US 5,384,103), Feldman (US 5,658,529), Smith (US 3,961,111), and Cohen (US 4,532,065). Deeds was cited for the teaching of a container substantially as claimed (without mention of the anodization layer). Miller was added for teaching making sterilization container components from anodized aluminum (without mention of the anodization layer

thickness). Feldman was cited as teaching subjecting anodized aluminum instruments to gas plasma sterilization. (These three were cited in the previous Office Action.) Upon Applicant's response that none of these taught the anodization layer thickness limitation (not greater than 0.5 mils), the Examiner added Smith and Cohen. Smith was cited for showing natural oxide coatings of 0.2 to 0.6 micro inches (0.0002 to 0.006 mils) on aluminum surfaces and a general range of 1-35 microns (0.04-1.4 mils) for aluminum surfaces and more particularly for 1-3 microns (0.04-0.12 mils) for paint bases and 5-10 microns (0.2 to 0.4 mils) for outdoor aluminum. Cohen was cited a teaching of 0.3 to 0.4 mils for automotive applications.

In the Interview, the Examiner pointed to the fact that the claims were unlimited in a lower amount and that intentionally leaving an unanodized container in an oxidizing environment would meet the independent claim limitation. Applicant therefore agreed to amend the claims by inserting a lower limit to the anodized coating thickness. Thus, Applicant amended the independent claims in this paper by requiring the anodized layer to have a lower limit of 0.2 mils. This rendered claims 24-26 duplicative of other claims, and thus, claims 24-26 have been cancelled.

With this amendment, all of the claims require an anodic coating to be present and that coating to be in the range of substantially not less than 0.2 mils and substantially not greater than 0.5 mils. Comparing this to the "natural" layers formed as disclosed in Smith (0.0002 to 0.0006 mils), it is readily apparent that Applicant's lower limitation (0.2 mils) is at least 330 times the maximum stated as naturally developing. Thus, the "natural oxide" layer is no longer within the claims. Furthermore, it is so far away from Applicant's lower limit that it cannot render that lower limit obvious. In fact, the Smith reference in the immediately following sentence states "these natural oxide films have little resistance to corrosion of any type and industry has resorted to the formation of artificial oxide films by anodizing." This is without a doubt a teaching away from the use of natural oxide films. In addition, the Smith reference teaches a general range of anodization layers of from 1 to 35 microns (0.04 mil to 1.4 mil); a total range of 1.36 mils.

Applicant's limitation of the anodization layer thickness is 0.2 to 0.5 mils; a total range of 0.3 mils. Neither Applicant's lower nor upper limit is taught or suggested by that general range, and the size of applicant's range (0.3 mils) is a mere 22.1% of the range indicated generally in the Smith reference. As such, there is nothing there that teaches or suggests the particular range claimed by Applicant.

The other two ranges of thicknesses indicated by the Smith reference deal with ranges associated with paint bases and outdoor aluminum. Neither of these application have anything to do with and have no appreciation for the limitations and considerations involved in obtaining efficacious sterilization, especially in a plasma sterilization context. Applicant pointed this out and the Examiner indicated that there was no criticality yet shown for the anodization layer thickness limitations. Applicant agreed to submit information to demonstrate that the considerations in the Smith types of applications would not give one of ordinary skill any particular motivation to apply those limitation to the other references in order to obtain sterilization containers of the present invention.

Cohen was cited for teaching an anodization layer of 0.3-0.4 mils in the automotive industry. Applicant pointed out that the automotive application would give one of ordinary skill any motivation to apply the same levels to the sterilization containers of the other art to arrive at the claimed invention.

Each of Smith and Cohen are directed to the protective nature of the anodization layer to the aluminum substrate. Use of this protective layer against corrosion in the automotive industry and in outdoor aluminum and as a paint base do not address the fact that anodization layer thicknesses as low as 0.6 mils effectively aborts the ability of the sterilization case to result in effective sterilization of the contents, especially in the context of gas plasma sterilization.

As further demonstrating the unobviousness of the current claims over the art, Applicant submits the enclosed Frieze Declaration, in which it is demonstrated that an

aluminum container having an anodization layer of 0.5 mils meets sterilization specifications, while one having an anodization layer thickness of 0.6 mils does not. Nowhere in any of the art of record is there any indication that such a limitation is involved. The sterilization container art merely indicates that anodization layers are useful. Some of that art refers to thin layers. Yet not one of the prior art of record in this case indicates what "thin" is in this context. Anodization of sterilization containers has been known for a considerable time. Yet for at least 13 years, no one demonstrated a sterilization container with an anodic coating that both protected the substrate from corrosion and simultaneously gave effective sterilization. Thus, a clearly long felt, but unmet need in the market has finally been addressed by the present invention. This is yet another basis for patentability. A more complete discussion of the unmet need is found in Applicant's amendment of July 7, 2005, which is incorporated herein by reference.

Thus, the current claims are patent over the art because (1) the references showing particular thicknesses of oxide coatings are not properly combinable with the other art; (2) the invention has met a long felt but unmet need in the art; and (3) the references of record do not have considerations which would lead one to conclude that the oxide layers therein would alleviate the problems of the sterilization container art.

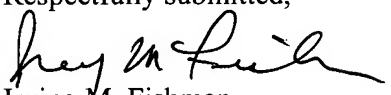
The Examiner also rejected the claims as obviousness double patenting over Applicant's US 6,589,477 in view of Feldman, Smith, and Cohen. Applicant submits that the above arguments defeat the application of Smith and Cohen to complete this rejection. Neither '477 nor Feldman state anything about the anodization layer thickness (Feldman being directed to instruments wherein the anodization layer is only concerned with protection against corrosion). Additionally, given the data presented in the accompanying declaration, the obviousness double patenting rejection cannot stand.

Finally, the Examiner provisionally rejected the claims over the claims of copending US 10/295,758. Applicant advised the Examiner in the Interview that upon an indication of allowance in the later of the two cases to be allowed, Applicant will either

create a clear dividing line between the two applications or file the appropriate terminal disclaimers. Prior to the allowance of the second to be allowed case, there is no double patenting issue. In the event that the Examiner requires a terminal disclaimer to be filed in both cases, Applicant affirmatively states that should a terminal disclaimer actually be necessary between the present case and copending US 10/295,758 (or its progeny) that the appropriate terminal disclaimer will be filed.

Based on the foregoing, Applicant submits that the present invention is in condition for allowance and respectfully requests that the examiner pass it to issue.

Respectfully submitted,



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